U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

**Date**: January 18, 2018

**From**: Adam C. Lanzarotta, Ph.D., Chemist
Organic Branch, Forensic Chemistry Center

**Subject**: Results of Analysis, OCI Case # 17-SLU-705-0123
OCI IE Serial # 17-0123-66086, FDA FACTS # 1030874
Mukileteo Police Department Case Number 1612976

**To**: Virginia Keys, Special Agent
Salt Lake Domicile Office, FDA/OCI

**Through**: Cheryl L. Flurer, Ph.D.
Director, Organic Branch, Forensic Chemistry Center

## I. Description of Samples Received for Analysis

Items 1 through 3, described in part on IE # 17-0123-66086, were received via UPS on 11/13/2017.

Item 1 consisted of twenty round, blue, tablets debossed with "M" enclosed in a square on one side and "30" on the half-scored side. One of the tablets was received in a plastic bag labeled "Analyzed", and was not further examined.

Item 2 consisted of one full tablet and three partial tablets. One of the partial tablets was received in a plastic bag labeled "Analysis", and was not further examined. The intact tablet was white, rectangular, quarter-scored on both sides and debossed with "XANAX" on one side and "2" on the other side. The two remaining partial tablets were white, rectangular, scored on both sides and debossed with "XA" on one side and with what appeared to be a partial "2" on the other side.

Item 3 consisted of two partial tablets. One of the partial tablets was received in a plastic bag labeled "Analyzed", and was not further examined. The remaining partial tablet was white, round and debossed with "O" on one side and "0" on the other side.

## II. Analytical Tests Performed on Samples

Per the Request for Laboratory Services and correspondence with SA Keys, tablets from Items 1 and 2 were examined for authenticity and for the presence of active pharmaceutical ingredients (APIs). The partial tablet from Item 3 was examined for the presence of APIs.

Nineteen tablets from Item 1 and one full tablet and two partial tablets from Item 2 were examined using an alternate light source (ALS). Three tablets from Item 1 and one tablet from Item 2 were examined using 3D instrumentation profilometry (3D IA) measurement (spatial and depth cross-section). Two tablets from Item 1, one full tablet and two partial tablets from Item 2, and a partial tablet from Item 3 were examined using Fourier transform infrared (FT-IR) spectroscopy. A two-tablet composite from Item 1, one full tablet and two partial tablets from Item 2, and a partial tablet from Item 3 were examined using gas chromatography with mass spectrometric (GC/MS) detection. One full tablet and two partial tablets from Item 2 were examined for the presence of fentanyl using liquid chromatography with mass spectrometric (LC/MS) detection.

Tablet imprint, image profiles and chemical composition comparisons of Items 1 and 2 to materials submitted under IEs # 17-0123-58447 (Sample 997004) and # 17-0123-18860 (Sample 1032983) will be presented in a coordinating report.

## III. Results and Conclusions

Item 1

Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other, but not consistent with the authentic oxycodone 30mg tablets manufactured by Mallinckrodt.

Using 3D IA, the spatial and depth cross-section of the debossings on three tablets were consistent with each other, but not consistent with those of authentic tablets.

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Using FT-IR spectroscopy, the infrared spectra of two tablet cores were consistent with each other but not consistent with that of an authentic tablet core.

Using GC/MS, U-47700 was identified in the two-tablet composite based on retention time and mass spectral comparisons with a standard. No other drugs, poisons, or pharmaceuticals were identified in the sample.

Item 2
Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other, but could not be differentiated from the authentic Xanax 2mg tablets manufactured by Pfizer. Using FT-IR spectroscopy, the infrared spectra of three tablet cores were consistent with each other but not consistent with that of an authentic tablet core.

Using 3D IA, the spatial and depth cross-section of the debossings on the full tablet were not consistent with those of authentic tablets.

Using GC/MS, U-47700 and alprazolam were identified in three tablets based on retention times and mass spectral comparisons with standards. No other drugs, poisons, or pharmaceuticals were identified in the sample.

Using LC/MS, fentanyl was not detected in the full tablet at a level equal to or greater than approximately 1.0 µg/tablet or in the partial tablets at a level equal to or greater than approximately 2.5 µg/tablet.

Item 3
Using FT-IR spectroscopy, the partial tablet core was consistent with the presence of quetiapine fumarate based on spectral comparison with a standard.

Using GC/MS, U-47700 and quetiapine were identified in the partial tablet based on retention times and mass spectral comparisons with standards. No other drugs, poisons, or pharmaceuticals were identified in the sample.

**IV. Sample Retention/Disposition/Feedback Information**
This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2236, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

Adam C. Lanzarotta, Ph.D.

**Section Authors' Concurrences**

Sections 1 and 702 _____
Adam C. Lanzarotta, Ph.D.

Section 680 _____
Heather A. McCauley

Section 638 _____
Nicola Ranieri

Section 716 _____
Travis Falconer, Ph.D.

JaCinta S. Batson, M.S., M.B.A _____
Supervisor

Sample # 1030874 1/18/2018

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

## Case/Sample Summary Report

**Date**: January 18, 2018

**From**: Adam C. Lanzarotta, Ph.D., Chemist
Organic Branch, Forensic Chemistry Center

**Subject**: Results of Analysis, OCI Case # 17-SLU-705-0123
OCI IE Serial # 17-0123-18860, FDA FACTS # 1032983
Wallingford Police Department Case/Receipt Number 16-24248

**To**: Virginia Keys, Special Agent
Salt Lake Domicile Office, FDA/OCI

**Through**: Cheryl L. Flurer, Ph.D.
Director, Organic Branch, Forensic Chemistry Center

### I. Description of Samples Received for Analysis

Item 1, described in part on IE # 17-0123-18860, was received via UPS on 12/1/2017.

Item 1 consisted of components of a pen and 52 round, blue, tablets debossed with "M" enclosed in a square on one side and "30" on the half-scored side.

### II. Analytical Tests Performed on Samples

Per the Request for Laboratory Services and correspondence with SA Keys, tablets from Item 1 were examined for authenticity and active pharmaceutical ingredients. All of the tablets were examined using an alternate light source (ALS). Three tablets were examined using 3D instrumentation profilometry (3D IA) measurement (spatial and depth cross-section). Two tablets were examined using Fourier transform infrared (FT-IR) spectroscopy and direct analysis in real time mass spectrometry (DART-MS). A five-tablet composite was examined using gas chromatography with mass spectrometric (GC/MS) detection. No analyses were conducted on the pen components.

### III. Results and Conclusions

Using ALS with the same lighting and filter settings, all of the suspect tablets were consistent with each other, but could not be differentiated from authentic oxycodone 30mg tablets manufactured by Mallinckrodt.

Using 3D IA, the spatial and depth cross-section of the debossings on three tablets were consistent with each other, but not consistent with those of authentic tablets.

Using FT-IR spectroscopy, the infrared spectra of two tablet cores were consistent with each other but not consistent with that of an authentic tablet core.

Using DART-MS, the two tablets were consistent with the presence of U-47700 based on mass spectral comparisons with a standard.

Using GC/MS, U-47700 was identified in the five-tablet composite based on retention time and mass spectral comparisons with a standard. No other drugs, poisons, or pharmaceuticals were identified in the sample.

Tablet imprint, image profiles and chemical composition comparisons of Item 1 to materials submitted under IEs # 17-0123-58447 (Sample 997004) and # 17-0123-66086 (Sample 1030874) will be presented in a coordinating report.

### IV. Sample Retention/Disposition/Feedback Information

This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2236, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

Adam C. Lanzarotta, Ph.D.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

**Section Authors' Concurrences**

Sections 1 and 702 _____
Adam C. Lanzarotta, Ph.D.

Section 680 _____
Heather A. McCauley

Section 638 _____
Nicola Ranieri

Section 716 _____
Travis Falconer, Ph.D.

JaCinta S. Batson, M.S., M.B.A _____
Supervisor

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

## Case/Sample Summary Report

**Date**: January 24, 2018

**From**: Mary B. Jones, Chemist
Inorganic Laboratory Branch

**Subject**: Results of Analysis
Case number 18-KCK-713-0029; OCI IE number 18-0029-99200
FACTS Sample 1036222

**To**: S.A. Virginia Keys
Kansas City Field Office, OCI

**Through**:
Douglas T. Heitkemper, Ph.D.
Director, Inorganic Laboratory Branch

### I. Description of Samples Received for Analysis

The sample was received via UPS on January 4, 2018. Sample 1036222 consisted of six items.

*Item 1:* Six intact blister packs labeled in part "***OL-TRAM® TABLETS***Tramadol Hydrochloride**100 mg**B.No.218-241***EXP.JUL-2020***". Each blister pack contained, 10 round, white tablets. One blister pack was opened by the lead analyst and additionally, the tablets were unmarked on both sides.

*Item 2:* Six intact blister packs labeled in part "***OL-TRAM® TABLETS***Tramadol Hydrochloride**100 mg**B.No.218-241***EXP.JUL-2020***". Each blister pack contained, 10 round, white tablets. One blister pack was opened by the lead analyst and additionally, the tablets were unmarked on both sides.

*Item 3:* Six intact blister packs labeled in part "***OL-TRAM® TABLETS***Tramadol Hydrochloride**100 mg**". Three of the blister packs were also labeled in part with "B.No.218-241***EXP.JUL-2020***". One from this lot number was designated as Sub 1 by the lead analyst. The other three blister packs were also labeled in part with "B.No.218-238***EXP.JUL-2020***". One from this lot number was designated as Sub 2 by the lead analyst. Each blister pack contained, 10 round, white tablets. One blister pack representing each lot number was opened by the lead analyst and additionally, the tablets were unmarked on both sides.

*Item 4:* Six intact blister packs labeled in part "***OL-TRAM® TABLETS***Tramadol Hydrochloride**100 mg**B.No.218-241***EXP.JUL-2020***". Each blister pack contained, 10 round, white tablets. One blister pack was opened by the lead analyst and additionally, the tablets were unmarked on both sides.

*Item 5:* Six intact blister packs labeled in part "***OL-TRAM® TABLETS***Tramadol Hydrochloride**100 mg**B.No.218-241***EXP.JUL-2020***". Each blister pack contained, 10 round, white tablets. One blister pack was opened by the lead analyst and additionally, the tablets were unmarked on both sides.

*Item 6:* Six intact blister packs labeled in part "***OL-TRAM® TABLETS***Tramadol Hydrochloride**100 mg**". Four of the blister packs were also labeled in part with "B.No.218-241***EXP.JUL-2020***". One from this lot number was designated as Sub 1 by the lead analyst. One blister pack was also labeled in part with "B.No.218-239***EXP.JUL-2020***". This lot number was designated as Sub 2 by the lead analyst. One blister pack was also labeled in part with "B.No.218-235**EXP.JUN-2020***". This lot number was designated as Sub 3 by the lead analyst. Each blister pack contained, 10 round, white tablets. One blister pack representing each lot number was opened by the lead analyst and additionally, the tablets were unmarked on both sides.

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**Case/Sample Summary Report**

**II. Analytical Tests Performed on Samples**

Per the Request for Laboratory Services and email correspondence, portions of Sample 1036222 Items 1 through 6 were analyzed for the presence of drugs and poisons using gas chromatography with mass spectral detection (GC-MS).

**III. Results and Conclusions**

A five tablet composite was prepared from Item 1, Item 2, Item 3 Subs 1 and 2, Item 4, Item 5, and Item 6 Subs 1 through 3. Duplicate portions of the composite were analyzed using GC-MS. Tramadol was identified in the Item 1, Item 2, Item 3 Subs 1 and 2, Item 4, Item 5, and Item 6 Subs 1 through 3 composite portions, based on retention time and mass spectral comparisons to a tramadol hydrochloride standard. No other drugs or poisons were identified in the Item 1, Item 2, Item 3 Subs 1 and 2, Item 4, Item 5, and Item 6 Subs 1 through 3 composite portions, under the experimental conditions used.

**Retention/Disposition/Feedback Information**

This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2210, or Jonathan J. Litzau at (513) 679-2700 Ext 2268.

Mary B. Jones

**Section Authors Concurrences**

Section 1/635: Mary B. Jones

Supervisor: Jonathan J. Litzau

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

**Date**: December 5, 2017

**From**: JaCinta S. Batson, Supervisory Chemist
Organic Branch, Forensic Chemistry Center, FDA

**Subject**: Status Report, OCI Case # 17-SLU-705-0123
OCI IE Serial # 17-0123-58447
FDA FACTS # 997004

**To**: Virginia Keys, Special Agent
Kansas City Field Office, OCI

**Through**: Cheryl L. Flurer, Ph.D.
Director, Organic Branch, Forensic Chemistry Center

This is a status report on the analysis of Items 1 through 22. The results of the remaining analyses will be provided in a future report.

**I. Description of Samples Received for Analysis**

Items 1 through 22, described in part on IE # 17-0123-58447, were received via UPS on February 1, 2017.

Items 1 through 5, 7 and 11 each consisted of five round, white tablets debossed with "A 215" on the half-scored side and blank on the opposite side.

Items 6, 8 through 10, 12 and 13 each consisted of five round, white tablets debossed with "M" enclosed in a square on one side and "30" on the half-scored side.

Items 14 through 19 each consisted of five rectangle, white tablets debossed with "GG 249" on the quarter-scored side and blank on opposite side.

Item 20 consisted of 24 metal tablet punches and 10 round metal tablet dies. The tablet punches consisted of the following:

- Two punches, further identified "Items 20A1 and 20A2", each had a rectangle punch face embossed with "GG 249" and quarter-scored.
- One punch, further identified "Item 20A3" had a round punch face and no embossed characters.
- Five punches, further identified "Items 20B1 through 20B4 and 20B11", each had a rectangle punch face embossed with "2" and quarter-scored.
- Five punches, further identified "Items 20B5 through 20B8 and 20B10", each had a rectangular punch face embossed with "XANAX" and quarter-scored.
- Five punches, further identified "Item 20B9, 20B17 through 20B20", each had an oblong punch face embossed with "10/325".
- Five punches, further identified "Item 20B12 through 20B16", each had an oblong punch face embossed with "M523".
- One punch, further identified "Item 20B21", had a rectangular punch face embossed with "R039" and quarter-scored.

Item 21 consisted of nine metal tablet punches, further identified "Item 21A1 through 21A9" each with a round punch face embossed "M" enclosed in a square.

Item 22 consisted of eight metal tablet punches, further identified "Items 22A1 through 22A8", each with a rectangle punch face embossed with "GG 249" and quarter-scored.

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Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

**II. Analytical Tests Performed on Samples**

Per the Request for Laboratory Services and communications with SA Keys, comparison analyses were performed using image analyses by 3D instrumentation profilometry measurements (spatial and depth cross-section) and difference measurements (overall surface morphology overlay) of the embossed tablet punch tips (TPT) from Items 20 through 22 and the corresponding debossed tablets from Items 6, 8 through 10, and 12 through 19. All of the tablets from Items 1 through 19 were visually compared to each other using an alternate light source (ALS). One representative tablet each from Items 1 through 19 was compared to a corresponding authentic tablet using ALS and Fourier transform infrared (FT-IR) spectroscopy.

Image analysis of the tablets from Items 1 through 5, 7 and 11, or the TPTs from Items 20A3 and 20B1 through 20B21, was not performed at this time. Any comparative analyses involving these Items will be reported in separate reports.

**III. Results and Conclusions**

Items 1 through 5, 7 and 11

All of the suspect tablets exhibited the same shape, color and debossing characteristics, and were compared to authentic oxycodone 30 mg tablets manufactured by Actavis. Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other, but they could not be differentiated from the authentic tablets. Using FT-IR spectroscopy, the infrared spectra of one tablet core from each Item were consistent with each other but were not consistent with that of an authentic oxycodone 30mg tablet core.

Items 6, 8 through 10, 12 and 13

All of the suspect tablets exhibited the same shape, color and debossing characteristics and were compared to authentic oxycodone 30 mg tablets manufactured by Mallinckrodt. Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other, but they could not be differentiated from the authentic tablets. Using FT-IR spectroscopy, the infrared spectra of one tablet core from each Item were consistent with each other but were not consistent with that of an authentic oxycodone 30mg tablet core.

All tablets in each Item were evaluated visually using the stereo light microscope to determine consistency. Within Item 6, two tablet types were observed (Tablets 2 and 3 selected as representatives). Within Items 8 through 10, 12 and 13, all tablets appeared the same; Tablet 1 was selected as representative for each Item. Using image analysis, comparisons were made among the nine TPTs in Item 21 and the representative tablets in Items 6, 8 through 10, 12 and 13, using TPT Item 21 Sub A1 as the example. All of the TPTs and tablets embossed/debossed with "M" enclosed in a square revealed consistent characteristic features between the embossing on TPTs from Item 21 Subs A1 through A9, and the debossing of Tablets 2 and 3 from Item 6, and Tablet 1 from Items 8 through 10, 12 and 13.

Items 14 through 19

All of the suspect tablets exhibited the same shape, color and debossing characteristics and were compared to an authentic alprazolam 2 mg tablet manufactured by Sandoz. Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other but could not be differentiated from the authentic tablets. Using FT-IR spectroscopy, the infrared spectra of one tablet core from each item were consistent with each other but not consistent with that of an authentic Alprazolam 2mg tablet core.

All tablets in each Item were evaluated visually using the stereo light microscope to determine consistency. Within Item 14, three tablet types were observed (Tablets 1, 2 and 3 selected as representatives). Within Items 15 and 16, two tablet types each were observed (Tablets 1 and 2 selected as representatives for each). Within Items 17 through 19, all tablets appeared the same; Tablet 1 was selected as representative for each Item. Using image analysis, comparisons were made among the two TPTs in Item 20 and eight TPTs in Item 22 and the representative tablets in Items 14 through 19, using TPT Item 20 Sub A2 as the example. All of the TPTs and tablets embossed/debossed with "GG 249" revealed consistent characteristic features of the embossing between TPTs from Item 20 Subs A1 and A2, Item 22 Subs A1 through A8, and the debossing of tablets from Tablets 1 through 3 from Item 14, Tablets 1 and 2 from Items 15 and 16, and Tablet 1 from Items 17 through 19.

U.S. Food and Drug Administration, Forensic Chemistry Center
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**Case/Sample Summary Report**

**IV. Sample Retention/Disposition/Feedback Information**

This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2212, or Dr. Cheryl L. Flurer at (513) 679-2700 Ext 2214.

JaCinta S. Batson, MS

**Section Authors Concurrences**

Section 673 — for S.F.P.
S. Frank Platek, MS

Section 638
Nicola Ranieri

Section 702
Adam C. Lanzarotta, Ph.D.

Adam C. Lanzarotta, Ph.D.
Reviewer

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

## Case/Sample Summary Report

**Date**: January 19, 2018

**From**: S. Frank Platek, Biologist
Organic Branch, Forensic Chemistry Center, FDA

**Subject**: Results of Analysis, OCI Case # 17-SLU-705-0123
OCI IE Serial # 17-0123-58447, DEA Case No. ML-16-0095,
FDA FACTS # 997004

**To**: Virginia Keys, Special Agent
Kansas City Field Office, OCI

**Through**: Cheryl L. Flurer, Ph.D.
Director, Organic Branch, Forensic Chemistry Center

This report is a supplement to the status report issued by JaCinta S. Batson to SA Virginia Keys on December 5, 2017. It includes results previously reported, and completes the analyses on the evidence submitted under IE # 17-0123-58447.

### I. Description of Samples Received for Analysis

Items 1 through 22, described in part on IE # 17-0123-58447, were received via UPS on February 1, 2017.

Items 1 through 5, 7 and 11 each consisted of five round, white tablets debossed with "A 215" on the half-scored side and blank on the opposite side.

Items 6, 8 through 10, 12 and 13 each consisted of five round, white tablets debossed with "M" enclosed in a square on one side and "30" on the half-scored side.

Items 14 through 19 each consisted of five rectangle, white tablets debossed with "GG 249" on the quarter-scored side and blank on opposite side.

Item 20 consisted of 24 metal tablet punches and 10 round metal tablet dies. The tablet punches consisted of the following:

- Two punches, further identified "Items 20A1 and 20A2", each had a rectangle punch face embossed with "GG 249" and quarter-scored.
- One punch, further identified "Item 20A3" had a round punch face and no embossed characters.
- Five punches, further identified "Items 20B1 through 20B4 and 20B11", each had a rectangle punch face embossed with "2" and quarter-scored.
- Five punches, further identified "Items 20B5 through 20B8 and 20B10", each had a rectangular punch face embossed with "XANAX" and quarter-scored.
- Five punches, further identified "Item 20B9, 20B17 through 20B20", each had an oblong punch face embossed with "10/325".
- Five punches, further identified "Item 20B12 through 20B16", each had an oblong punch face embossed with "M523".
- One punch, further identified "Item 20B21", had a rectangular punch face embossed with "R039" and quarter-scored.

Item 21 consisted of nine metal tablet punches, further identified "Item 21A1 through 21A9" each with a round punch face embossed "M" enclosed in a square.

Item 22 consisted of eight metal tablet punches, further identified "Items 22A1 through 22A8", each with a rectangle punch face embossed with "GG 249" and quarter-scored.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

## II. Analytical Tests Performed on Samples

Per the Request for Laboratory Services and communications with SA Keys, tablets from Items 1 through 19 were examined for authenticity and for the presence of active pharmaceutical ingredients (APIs). All of the tablets from Items 1 through 19 were visually compared to each other and to corresponding authentics using an alternate light source (ALS). One tablet each from Items 1 through 19 was analyzed using Fourier transform infrared (FT-IR) spectroscopy and direct analysis in real time mass spectrometry (DART-MS). Three-tablet composites from Items 1 through 19 were examined using gas chromatography with mass spectrometric (GC/MS) detection. The three-tablet composites from Items 14 through 19 were also examined for the presence of fentanyl using liquid chromatography with mass spectrometric (LC/MS) detection.

Comparison analyses were performed using image analyses by 3D instrumentation profilometry measurements (spatial and depth cross-section) and difference measurements (overall surface morphology overlay) of the embossed tablet punch tips (TPT) from Items 20 through 22 and the corresponding debossed tablets from Items 6, 8 through 10, and 12 through 19. No comparison analyses were conducted for the tablets and punch tips from Items 1 through 5, 7, 11, 20A3, 20B9, 20B12 through 20B21.

Mikrosil castings from Items 20B1 through 20B8, 20B10 and 20B11 were made for comparison to IE # 17-0123-66086 Item 2. The results from these analyses will be presented in a coordinating report.

## III. Results and Conclusions

Items 1 through 5, 7 and 11

All of the suspect tablets exhibited the same shape, color and debossing characteristics, and were compared to authentic oxycodone 30 mg tablets manufactured by Actavis. Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other, but they could not be differentiated from the authentic tablets. Using FT-IR spectroscopy, the infrared spectra of one tablet core from each Item were consistent with each other but were not consistent with that of an authentic oxycodone 30mg tablet core.

Using GC/MS and DART-MS, fentanyl was identified in Items 1 through 5, 7 and 11 based on retention time and mass spectral comparisons with a standard. Using GC/MS, no other drugs, poisons, or pharmaceuticals were identified in the samples.

Items 6, 8 through 10, 12 and 13

All of the suspect tablets exhibited the same shape, color and debossing characteristics and were compared to authentic oxycodone 30 mg tablets manufactured by Mallinckrodt. Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other, but they could not be differentiated from the authentic tablets. Using FT-IR spectroscopy, the infrared spectra of one tablet core from each Item were consistent with each other but were not consistent with that of an authentic oxycodone 30mg tablet core.

All tablets in each Item were evaluated visually using the stereo light microscope to determine consistency. Within Item 6, two tablet types were observed (Tablets 2 and 3 selected as representatives). Within Items 8 through 10, 12 and 13, all tablets appeared the same; Tablet 1 was selected as representative for each Item. Using image analysis, comparisons were made among the nine TPTs in Item 21 and the representative tablets in Items 6, 8 through 10, 12 and 13, using TPT Item 21 Sub A1 as the example. All of the TPTs and tablets embossed/debossed with "M" enclosed in a square revealed consistent characteristic features between the embossing on TPTs from Item 21 Subs A1 through A9, and the debossing of Tablets 2 and 3 from Item 6, and Tablet 1 from Items 8 through 10, 12 and 13.

Using GC/MS and DART-MS, fentanyl was identified in Items 6, 8 through 10, 12 and 13 based on retention time and mass spectral comparisons with a standard. Using GC/MS, no other drugs, poisons, or pharmaceuticals were identified in the samples.

Items 14 through 19

All of the suspect tablets exhibited the same shape, color and debossing characteristics and were compared to an authentic alprazolam 2 mg tablet manufactured by Sandoz. Using ALS with the same wavelength and filter settings, all of the suspect tablets were consistent with each other but could not be differentiated from the authentic tablets. Using FT-IR spectroscopy, the infrared spectra of one tablet core from each item were consistent with each other but not consistent with that of an authentic Alprazolam 2mg tablet core.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

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All tablets in each Item were evaluated visually using the stereo light microscope to determine consistency. Within Item 14, three tablet types were observed (Tablets 1, 2 and 3 selected as representatives). Within Items 15 and 16, two tablet types each were observed (Tablets 1 and 2 selected as representatives for each). Within Items 17 through 19, all tablets appeared the same; Tablet 1 was selected as representative for each Item. Using image analysis, comparisons were made among the two TPTs in Item 20 and eight TPTs in Item 22 and the representative tablets in Items 14 through 19, using TPT Item 20 Sub A2 as the example. All of the TPTs and tablets embossed/debossed with "GG 249" revealed consistent characteristic features of the embossing between TPTs from Item 20 Subs A1 and A2, Item 22 Subs A1 through A8, and the debossing of tablets from Tablets 1 through 3 from Item 14, Tablets 1 and 2 from Items 15 and 16, and Tablet 1 from Items 17 through 19.

Using GC/MS and DART-MS, alprazolam was identified in Items 14 through 19 based on retention time and mass spectral comparisons with a standard. Using GC/MS, no other drugs, poisons, or pharmaceuticals were identified in the samples.

Using LC/MS, fentanyl was not detected in Items 14 through 19 at a level equal to or greater than approximately 1.3 µg/tablet.

**IV. Sample Retention/Disposition/Feedback Information**

This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2254, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

S. Frank Platek, MS

**Section Authors Concurrences**

Section 1, 673 — S. Frank Platek, MS

Section 638 — Nicola Ranieri

Section 702 — Adam C. Lanzarotta, Ph.D.

Section 716, 716A — Travis Falconer, Ph.D.

Section 680 — Heather A. McCauley for HAM

JaCinta S. Batson, MS
Supervisory Chemist

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

# Coordinating Report

**Date**: January 30, 2018

**From**: Adam C. Lanzarotta, Ph.D., Chemist
Organic Branch, Forensic Chemistry Center

**Subject**: Coordinating Report for:

| OCI case # | OCI IE # | FDA FACTS # | Other Agency Number |
|---|---|---|---|
| 17-SLU-705-0123 | 17-0123-58447 | 997004 | DEA File No. ML 160095 |
| | 17-0123-66086 | 1030874 | Mukilteo Police Case Number 1612976 |
| | 17-0123-18860 | 1032983 | Wallingford Police Case/Receipt Number 16-24248 |

**To**: Virginia Keys, Special Agent
Salt Lake Domicile Office, FDA/OCI

**Through**: Cheryl L. Flurer, Ph.D.
Director, Organic Branch, Forensic Chemistry Center

This Coordinating Report provides results of comparative analyses on items submitted under IE #s 17-0123-58447, 17-0123-66086 and 17-0123-18860.

Table 1 summarizes the items having markings "M" and/or "30":

| OCI IE # | FDA FACTS # | Item # | Item |
|---|---|---|---|
| 17-0123-58447 | 997004 | Item 21 Subs A1 through A9 | Tablet punch tips |
| | | Items 6, 8, 9, 10, 12 and 13 | Tablets |
| 17-0123-66086 | 1030874 | Item 1 | Tablets |
| 17-0123-18860 | 1032983 | Item 1 | Tablets |

Table 2 summarizes the items having markings "XANAX" and/or "2":

| OCI IE # | FDA FACTS # | Item # | Item |
|---|---|---|---|
| 17-0123-58447 | 997004 | Item 20 Subs B1 through B8, B10 and B11 | Tablet punch tips |
| 17-0123-66086 | 1030874 | Item 2 | Tablets |

## Results and Conclusions

The tablet punch tips listed in Tables 1 and 2 were examined using 3D instrumentation profilometry (3D IA) measurement (spatial and depth cross-section). The tablets listed were examined using 3D IA, gas chromatography with mass spectrometric detection (GC/MS), direct analysis in real-time with mass spectrometric detection (DART-MS), liquid chromatography with mass spectrometric detection (LC/MS) and/or Fourier transform infrared (FT-IR) spectroscopy.

## "M" and/or "30"

Image Analysis

Using 3D IA (spatial and depth cross-section) overlay, the tablet punch tips from IE #17-0123-58447 Item 21 revealed consistent characteristic features with representative tablets from IE #17-0123-58447 Items 6, 8, 9, 10, 12 and 13.

The tablet punch tips did not display consistent characteristic features with representative tablets from IE #17-0123-66086 Item 1 or IE #17-0123-18860 Item 1.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
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**Coordinating Report**

The representative tablets from IE #17-0123-66086 Item 1 and IE #17-0123-18860 Item 1 revealed consistent characteristic features with each other.

Chemical Composition Comparisons
Using FT-IR spectroscopy, the infrared spectra from one tablet core each from IE #17-0123-58447 Items 6, 8-10, 12 and 13 were consistent with each other but were not consistent with two tablet cores each from IE #17-0123-66086 Item 1 and IE #17-0123-18860 Item 1. Using GC/MS and DART-MS, fentanyl was identified in tablets in the items from IE #17-0123-58447 based on retention time and mass spectral comparisons with a standard.

Using FT-IR spectroscopy, the infrared spectra of two tablet cores each from IE #17-0123-66086 Item 1 and IE #17-0123-18860 Item 1 were consistent with each other. Using GC/MS, U-47700 was identified in the tablets from IE #17-0123-66086 Item 1 and IE #17-0123-18860 Item 1 based on retention time and mass spectral comparisons with a standard.

**"XANAX" and "2"**
Using 3DIA profilometry overlay, one tablet from IE #17-0123-66086 Item 2 revealed inconsistent characteristic features when compared to the tablet punch tips from IE #17-0123-58447 Item 20.

Using GC/MS, U-47700 and alprazolam were identified in the tablets from IE #17-0123-66086 Item 2.

**IV. Sample Retention/Disposition/Feedback Information**
These samples will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2236, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

Adam C. Lanzarotta, Ph.D.

**Section Authors' Concurrences**

IE #s 17-0123-58447, 17-0123-66086 and 17-0123-18860

Sections 638, 638a
Nicola Ranieri

Section 702A
Adam C. Lanzarotta, Ph.D.

Section 716
Travis Falconer, Ph.D.

Section 680
Heather A. McCauley

JaCinta S. Batson, M.S., M.B.A.
Supervisor

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

# Coordinating Report

**Date**: October 11, 2018

**From**: S. Frank Platek, Biologist
Organic Branch, Forensic Chemistry Center, FDA

**Subject**: Coordinating Report for:

| OCI case # | OCI IE # | FDA FACTS # | Other Agency Number |
|---|---|---|---|
| 17-SLU-705-0123 | 17-0123-58447 | 997004 | DEA File No. ML 160095 |
| | 17-0123-12393 | 1048511 | Daly City Police Case/Receipt 16005199 |

**To**: Virginia Keys, Special Agent
Kansas City Field Office, FDA/OCI

**Through**: Jennifer L. Brzezinski, Ph.D.
Acting Director, Organic Branch, Forensic Chemistry Center

This Coordinating Report provides results of comparative analyses on Items submitted under IE #s 17-0123-58447 and 17-0123-12393.

Table 1 summarizes the Items having markings "GG 249":

| OCI IE # | FDA FACTS # | Item # | Item |
|---|---|---|---|
| 17-0123-58447 | 997004 | Items 14 through 19 | Tablets |
| | | Item 20 Subs A1 and A2<br>Item 22 Subs A1 through A8 | Tablet Punch Tips |
| 17-0123-12393 | 1048511 | Item 1b | Partial Tablet |
| | | Item 1c | Tablet |

## Results and Conclusions

The tablet punch tips listed in Table 1 were examined using image analysis (IA) by 3D profilometry and difference measurements. The tablets listed were examined using 3D IA, gas chromatography with mass spectrometric detection (GC/MS), direct analysis in real-time with mass spectrometric detection (DART-MS), liquid chromatography with mass spectrometric detection (LC/MS) and/or Fourier transform infrared (FT-IR) spectroscopy.

### Image Analysis

The embossing characteristics of the tablet punch tips from IE # 17-0123-58447 Item 20 Subs A1 and A2 and Item 22 Subs A1 through A8 and the debossing characteristics of the tablets from IE # 17-0123-58447 from Items 14 through 19 were consistent with each other when examined using 3D IA profilometry and difference measurements.

The embossing characteristics of the tablet punch tip from IE # 17-0123-58447 Item 20 Sub A2 was not consistent with the debossed characteristics of the tablet from IE # 17-0123-12393 Item 1c when examined using 3D IA profilometry and difference measurements.

### Chemical Composition Comparisons

Using FT-IR spectroscopy, the infrared spectra of the tablet cores from IE# 17-0123-58447 Items 14 through 19 were not consistent with the infrared spectrum of the tablet core from IE # 17-0123-12393 Item 1b.

Using GC/MS and DART-MS analyses, alprazolam was identified in the tablets from IE# 17-0123-58447, Items 14 through 19 based on retention time and mass spectral comparisons to a standard.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
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## Coordinating Report

Using GC/MS and LC/MS analyses, alprazolam and efavirenz were identified in the tablet from IE # 17-0123-12393 Item 1c based on retention times and mass spectral comparisons to standards.

**Sample Retention/Disposition/Feedback Information**
These samples will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2254, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

S. Frank Platek, M.S.

**Section Authors' Concurrences**

IE # 17-0123-58447

Section 1a — S. Frank Platek, M.S.

Section 638a — Nicola Ranieri

Section 680 — Heather A. McCauley

Section 702b — Adam C. Lanzarotta, Ph.D.

Sections 716, 716A — Travis Falconer, Ph.D.

IE # 17-0123-12393

Section 1a — S. Frank Platek, M.S.

Section 638a — Nicola Ranieri

Section 702 — Adam C. Lanzarotta, Ph.D.

Sections 707, 707a, 707b — Sarah E. Voelker, M.S.

JaCinta S. Batson, M.S., M.B.A.
Supervisor

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

**Date**: August 27, 2018

**From**: S. Frank Platek, Biologist
Organic Branch, Forensic Chemistry Center, FDA

**Subject**: Results of Analysis, OCI Case # 17-SLU-705-0123,
OCI IE Serial # 17-0123-12393, FDA FACTS # 1048511
Daly City Police Department – Case #: 16005199

**To**: Virginia Keys, Special Agent
Kansas City Field Office, OCI

**Through**: Cheryl L. Flurer, Ph.D.
Director, Organic Branch, Forensic Chemistry Center

## I. Description of Samples Received for Analysis

Items 1 and 2, described in part on IE # 17-0123-12393, were received via UPS on April 5, 2018.

Item 1 consisted of one amber-colored pharmaceutical bottle with an attached white plastic cap. The bottle contained the following items further identified by the analyst:

- Item 1a: consisted of one white, oval tablet debossed with "4H2" on one side.
- Item 1b: consisted of one partial white, rectangular scored tablet debossed with "GG 2" on one side.
- Item 1c: consisted of one white, rectangular ¼ scored tablet debossed with "GG 2 4 9" on one side.
- Item 1d: consisted of one white, oblong tablet printed with "alza 36" in black ink.
- Item 1e: consisted of seven light-tan, oblong tablets debossed with "G193" on one side and three light-tan, oblong tablets debossed with "RR144" on one side.

Item 2 consisted of one zip-top style bag containing a white powder.

## II. Analytical Tests Performed on Samples

Per the Request for Laboratory Services and communications with SA Keys, Item 1b was analyzed for authenticity using alternate light sources (ALS), image analyses (IA) by 3D instrumentation, handheld Raman (HHR) and Fourier transform infrared (FT-IR) spectroscopy. Item 1c was analyzed for authenticity using ALS and 3D IA. Items 1c and 2 were analyzed for the presence of active pharmaceutical ingredients using gas chromatography with mass spectrometric detection (GC-MS) and liquid chromatography with mass spectral detection (LC-MS). No analyses were conducted on Items 1a, 1d or 1e.

## III. Results and Conclusions

Using ALS analysis with the same wavelength and filter settings, Items 1b and 1c were visually consistent with each other and visually consistent with an authentic Alprazolam 2 mg (Sandoz) tablet.

The debossing characteristics of the partial tablet from Item 1b and the intact tablet from Item 1c were consistent with each other, but were not consistent with authentic Alprazolam 2mg tablets when examined using 3D IA profilometry and difference measurements.

Using HHR and FT-IR spectroscopy, the spectra of the partial tablet from Item 1b were not consistent with that of an authentic tablet.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Case/Sample Summary Report**

Using GC-MS and LC-MS analyses, alprazolam and efavirenz were identified in Item 1c based on retention times and mass spectral comparisons to respective reference standards. Using GC-MS, no additional drugs or poisons were identified under the experimental conditions used.

Using GC-MS and LC-MS analyses, alprazolam and nordiazepam were identified in Item 2 based on retention times and mass spectral comparisons to respective reference standards. Using GC-MS, no additional drugs or poisons were identified under the experimental conditions used.

**IV. Sample Retention/Disposition/Feedback Information**

This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2254, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

S. Frank Platek, MS

**Section Authors Concurrences**

Sections 1, 1a, 673 — S. Frank Platek, MS

Section 638 — Nicola Ranieri

Sections 707, 707a, 707b — Sarah E. Voelker, MS

Section 753 — Martin M. Kimani, Ph. D.

JaCinta S. Batson, MS, MBA
Supervisory Chemist

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

# Coordinating Report

**Date**: October 11, 2018

**From**: S. Frank Platek, Biologist
Organic Branch, Forensic Chemistry Center, FDA

**Subject**: Coordinating Report for:

| OCI case # | OCI IE # | FDA FACTS # | Other Agency Number |
|---|---|---|---|
| 17-SLU-705-0123 | 17-0123-58447 | 997004 | DEA File No. ML 160095 |
| | 17-0123-12393 | 1048511 | Daly City Police Case/Receipt 16005199 |

**To**: Virginia Keys, Special Agent
Kansas City Field Office, FDA/OCI

**Through**: Jennifer L. Brzezinski, Ph.D.
Acting Director, Organic Branch, Forensic Chemistry Center

This Coordinating Report provides results of comparative analyses on Items submitted under IE #s 17-0123-58447 and 17-0123-12393.

Table 1 summarizes the Items having markings "GG 249":

| OCI IE # | FDA FACTS # | Item # | Item |
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| 17-0123-12393 | 1048511 | Item 1b | Partial Tablet |
| | | Item 1c | Tablet |

**Results and Conclusions**

The tablet punch tips listed in Table 1 were examined using image analysis (IA) by 3D profilometry and difference measurements. The tablets listed were examined using 3D IA, gas chromatography with mass spectrometric detection (GC/MS), direct analysis in real-time with mass spectrometric detection (DART-MS), liquid chromatography with mass spectrometric detection (LC/MS) and/or Fourier transform infrared (FT-IR) spectroscopy.

Image Analysis

The embossing characteristics of the tablet punch tips from IE # 17-0123-58447 Item 20 Subs A1 and A2 and Item 22 Subs A1 through A8 and the debossing characteristics of the tablets from IE # 17-0123-58447 from Items 14 through 19 were consistent with each other when examined using 3D IA profilometry and difference measurements.

The embossing characteristics of the tablet punch tip from IE # 17-0123-58447 Item 20 Sub A2 was not consistent with the debossed characteristics of the tablet from IE # 17-0123-12393 Item 1c when examined using 3D IA profilometry and difference measurements.

Chemical Composition Comparisons

Using FT-IR spectroscopy, the infrared spectra of the tablet cores from IE# 17-0123-58447 Items 14 through 19 were not consistent with the infrared spectrum of the tablet core from IE # 17-0123-12393 Item 1b.

Using GC/MS and DART-MS analyses, alprazolam was identified in the tablets from IE# 17-0123-58447, Items 14 through 19 based on retention time and mass spectral comparisons to a standard.

U.S. Food and Drug Administration, Forensic Chemistry Center
6751 Steger Drive, Cincinnati, Ohio 45237-3097
Telephone: (513) 679-2700 FAX: (513) 679-2761

**Coordinating Report**

Using GC/MS and LC/MS analyses, alprazolam and efavirenz were identified in the tablet from IE # 17-0123-12393 Item 1c based on retention times and mass spectral comparisons to standards.

**Sample Retention/Disposition/Feedback Information**

These samples will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2254, or JaCinta S. Batson at (513) 679-2700 Ext 2212.

S. Frank Platek, M.S.

**Section Authors' Concurrences**

IE # 17-0123-58447

Section 1a — S. Frank Platek, M.S.

Section 638a — Nicola Ranieri

Section 680 — Heather A. McCauley

Section 702b — Adam C. Lanzarotta, Ph.D.

Sections 716, 716A — Travis Falconer, Ph.D.

IE # 17-0123-12393

Section 1a — S. Frank Platek, M.S.

Section 638a — Nicola Ranieri

Section 702 — Adam C. Lanzarotta, Ph.D.

Sections 707, 707a, 707b — Sarah E. Voelker, M.S.

JaCinta S. Batson, M.S., M.B.A.
Supervisor